FEB 2 2 2001

K002758

510(k) Summary
(As required by 21 C.F.R. §807.92)

The submitter of this premarket notification is:

Egon Pfeil
Regulatory Affairs
Agilent Technologies
Deutschland GmbH
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Germany
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This summary was prepared on: July 26, 2000

Device name: Agilent family of Patient Monitors individually known as the M1175A/76A/77A (CMS), Rev.L.

Common name: Patient Monitor

Classification names

Regulation Number	Classification Name
870.1435	Computer, Diagnostic, Pre-Programmed, Single-Function
870.1025	Detector and Alarm, Arrhythmia
870.2900	Cable, Transducer and Electrode, Patient (including connector)
870.1110	Computer, Blood-Pressure
870.2850	Transducer, Blood Pressure, Extravascular
870.1110	Computer, Blood Pressure
870.1025	Physiological Monitor, Patient

Predicate Devices: The modified device is substantially equivalent to the Hewlett Packard device marketed pursuant to K992595, and Pulsion Medical Systems AG PiCCO K001762 and K991886.

Modifications: The primary modification is an applications software based change that involves the utilization of an algorithm for the measurement of Cardiac Output (C.O.) and Intrathoracic Blood Volume (ITBV), using an transpulmonary thermodilution catheter and Continuous Cardiac Output (CCO) based on Pulse Contour Analysis of the arterial pressure wave using the same catheter and a pressure transducer kit. Additionally, new cabling accessories are added to accommodate the CCO application.

Intended Use: The new device has the same intended use as the legally marketed predicate devices. When used in the hospital environment, the device is intended for measuring and

	displaying, recording and alarming multiple physiological parameters and waves in adult, pediatric and neonatal patients.
Technological characteristics	The new device has the same technological characteristics as the legally marketed predicate devices.
Testing	Verification, validation, and testing activities were conducted to establish the performance and reliability characteristics of the new algorithm, including the use of simulated data to confirm performance specifications. Testing involved system level tests, integration tests, safety testing from hazard analysis, interference testing, and hardware testing. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Egon Pfeil
Regulatory Affairs
Agilent Technologies
Deutschland GmbH
Herrenberger Strasse 130
D-71034 Boeblingen
Germany

Re: K002758
Trade Name: Agilent Component Monitoring System, Rev. L (Rel.C.0), Models M1175A, M1176A, M1177A
Regulatory Class: III (three)
Product Code: DSI
Regulation: 870.1025
Dated: November 21, 2000
Received: November 27, 2000

Dear Mr. Pfeil:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

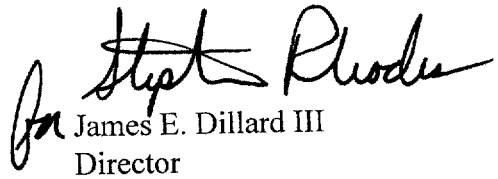
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS

inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number
(if known)

Device Name The Agilent Technologies CMS patient monitor, Rev.L., Models M1175A, M1176A, M1177A

Indications for Use The Agilent CMS patient monitor is intended for monitoring, recording, and alarming of multiple physiological parameters. The devices are indicated for use in health care facilities by health care professionals whenever there is a need for monitoring the physiological parameters of adult, neonatal, and pediatric patients.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K002758

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)